IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	C.A. No. 05-356 (KAJ)
	)	(consolidated)

MEMORANDUM IN SUPPORT OF DEFENDANT MYLAN'S RULE 12(c) MOTION FOR JUDGMENT ON THE PLEADINGS DISMISSING PLAINTIFFS' WILLFUL INFRINGEMENT CLAIM OR, IN THE ALTERNATIVE, TO BIFURCATE AND STAY DISCOVERY ON SUCH CLAIM

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I. INTRODUCTION.

This Court should enter judgment on the pleadings for Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc. (collectively, "Mylan") dismissing Janssen Pharmaceutica N.V.'s, Janssen, L.P.'s and Synaptech, Inc.'s (collectively, "Janssen") willful infringement claim pursuant to Rule 12(c), FED. R. CIV. P. In the alternative, this Court should enter an order, pursuant to Rule 42(b), FED. R. CIV. P., bifurcating and staying discovery on such claims until after a ruling on the merits of Janssen's infringement complaint.

With respect to Mylan's Rule 12(c) motion, this is not a case of first impression. On July 26, 2005, in a case involving virtually identical facts and allegations, Judge Sleet followed controlling Federal Circuit precedent when holding that a claim for willful patent infringement cannot, as a matter of law, be made solely on the basis of a so-called "paragraph IV certification." *See Allergan, Inc. v. Alcon Inc.*, No. 04-968 (GMS), at 3-4 (D. Del. July 26, 2005) (Sleet, J.) (striking plaintiff's willful infringement claim) (Ex. A)[1]. When confronted with this same issue, other district courts have followed the same controlling Federal Circuit precedent, *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), to dismiss or strike the plaintiff's willful infringement claims. The same relief should be granted here.

In this case, Janssen's only alleged basis for its willful infringement claim is that Mylan has filed an abbreviated new drug application ("ANDA") for a generic galantamine hydrobromide product containing a paragraph IV certification to the patent-in-suit. In view of the Federal Circuit and district court precedent on willful infringement claims in the ANDA context, no set of facts in its complaint supports Janssen's willful infringement allegation and

[1] References to "Ex. _" are to the Compendium of Unreported Opinions Relating to Mylan's Rule 12(c) Motion filed contemporaneously herewith.

claim for relief. Accordingly, this Court should grant Mylan judgment on the pleadings, dismissing Janssen's willful infringement claim pursuant to Rule 12(c).

In the alternative, this Court should bifurcate and stay discovery on Janssen's willfulness claim. This too is not a case of first impression. The majority of courts considering such motions in ANDA cases have granted such relief. The reasons for doing so are clear cut: Only by granting such relief can this Court (a) prevent the substantial prejudice that Mylan (and the other Defendants) would suffer from having to defend against such a claim before liability is established, and (b) conserve valuable resources of this Court and the parties. While this Court indicated at the October 12, 2005 status conference that it "typically" does not bifurcate willfulness claims, the Court stated that "there may well be a case where it needs to happen." (10/12/05 Tr. at 16, D.I. 25). This is such a case. Indeed, Mylan demonstrates below the "strong showing" supporting bifurcation in this consolidated action.

Further, the relief that Mylan seeks is in line not only with the Federal Circuit's decision in *Quantum Corp. v. Tandon Corp.*, 940 F.2d 642 (Fed. Cir. 1991), but the weight of district court authority on this issue, including decisions from this District—decisions illustrating that bifurcation in patent cases "has become common." *See Allergan Inc. v. Pharmacia Corp.*, No. Civ.A.01-141-SLR, 2002 WL 1268047, at *2 n.1 (D. Del. May 17, 2002) (Robinson, C.J.) (bifurcating and staying willful infringement discovery in an ANDA case) (Ex. B); *St. Clair Intellectual Prop. Consultants, Inc. v. Sony Corp.*, No. Civ.A.01-557-JJF, 2002 WL 1901268, at *2 (D. Del. Aug. 16, 2002) (Farnan, J.) (bifurcating and staying discovery on willfulness) (Ex. C); *Arthrocare Corp. v. Smith & Nephew, Inc.*, No. 01-504-SLR, slip op. at 3 (D. Del. Nov. 27, 2002) (Robinson, C.J.) (same) (Ex. D); *see also Corning Inc. v. SRU Biosystems, LLC*, 223

F.R.D. 189, 191 (D. Del. 2004) (Farnan, J.) (discussing the court's prior order bifurcating willfulness and staying discovery).

II. BACKGROUND.

This action arises under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress enacted Hatch-Waxman to "get generic drugs into the hands of patients at reasonable prices–fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). To achieve that goal, Congress created the ANDA procedure and "a mechanism to facilitate the adjudication of claims of infringement of patents relating to the innovator's drugs" before the generic drug has been marketed. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003).

A company seeking approval of the U.S. Food and Drug Administration ("FDA") to sell a previously-unapproved drug must file a new drug application ("NDA") with complete studies of safety and efficacy. *See* 21 U.S.C. § 355(b)(1). An NDA also must include the number and expiration date of any patent that "claims the drug for which the applicant submitted the application . . . ." 21 U.S.C. § 355(b)(1), (c)(2). FDA publishes this information in what commonly is known as the "Orange Book."

A company seeking FDA approval to market a generic version of an NDA drug files an ANDA with FDA. The ANDA includes information sufficient to show that the generic version is bioequivalent to its brand-name counterpart. *See generally* 21 U.S.C. § 355(j)(2). An ANDA also must contain a "certification" to any patent that the brand company has submitted for listing in the Orange Book. *See* 21 U.S.C. § 355(j)(2)(A)(vii). With certain exceptions not applicable here, an ANDA applicant that seeks approval to market a generic drug before expiration of the listed patent must submit a so-called "paragraph IV certification," stating that

the listed patent is invalid and/or will not be infringed by the ANDA product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Filing a paragraph IV ANDA is "a highly artificial act of infringement" under 35 U.S.C. § 271(e). *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). The "very limited and technical purpose" of this "highly artificial act" is "to permit patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue." *Glaxo*, 376 F.3d at 1349, 1351 (internal quotations and citations omitted). Section 271(e)(2) is, therefore, a jurisdictional provision, vesting the federal courts with subject matter jurisdiction over a patent-infringement action involving an ANDA drug that has not yet been marketed. *See id.* at 1351.[2] While 35 U.S.C. § 271(e)(2) allows patentees to sue *potential* infringers (*i.e.*, ANDA-filers) for patent infringement, the statute expressly restricts their remedies to equitable and declaratory relief in the absence of any actual sales of the generic drug. *See* 35 U.S.C. § 271(e)(4). Consequently, an ANDA applicant does not actually infringe a listed patent until it markets a generic drug product that infringes a valid and enforceable patent.

III. NATURE AND STAGE OF THE PROCEEDINGS.

This consolidated Hatch-Waxman patent case concerns just two claims from a single method-of-use patent, which expires on December 14, 2008. Janssen filed this patent infringement action. Defendants responded with counterclaims of invalidity. Recently, in an effort to obtain an earlier trial date, Defendants presented Janssen with a Stipulation Not to Contest Infringement (D.I. 49), which substantially limits the scope of this litigation. Janssen ultimately accepted that Stipulation. Accordingly, Defendants currently are seeking relief from the Court to truncate the current Scheduling Order (D.I. 30), entered on October 21, 2005, in

[2] If filed, such a suit automatically stays final FDA approval of the ANDA for up to 30 months, or until a court decision of non-infringement and/or invalidity is rendered, whichever is earlier. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

light of their Stipulation of infringement and the Court's comments during the October 12, 2005 status conference. A teleconference is scheduled with the Court for December 20, 2005, concerning these scheduling issues.

IV. SUMMARY OF ARGUMENT.

Janssen alleges that Mylan willfully infringed the '318 patent based solely upon Mylan's ANDA filing and its paragraph IV certification. (Compl. ¶¶ 31, 32, 34). Janssen has not, and cannot, make any other allegations to support its willfulness claim because Mylan has never sold the accused product. The Federal Circuit has held that the mere fact that a company has filed an application containing a paragraph IV certification cannot, as a matter of law, support a finding of willful patent infringement. *See Glaxo*, 376 F.3d at 1350-51. District courts, including this District, have dismissed or stricken willful infringement claims made against ANDA applicants/paragraph IV filers. *See Allergan*, No. 04-968 (GMS), at 4 (Ex. A). This Court should do the same here, strike or dismiss Janssen's willfulness claim.

In the alternative, Janssen's willfulness claim should be bifurcated, and discovery on the claim stayed, pending resolution of the merits of this action in order to avoid severely prejudicing Mylan and in the interest of judicial economy. Such relief, too, is consistent with controlling Federal Circuit case law, as well as decisions from this District. *See Quantum*, 940 F.2d at 643-44; *Pharmacia*, 2002 WL 1268047, at *2 n.1 (Ex. B); *St. Clair*, 2002 WL 1901268, at *2 (Ex. C); *Arthrocare*, No. 01-504-SLR, slip op. at 3 (Ex. D).

V. STATEMENT OF FACTS.

Janssen holds approved NDA No. 21-169 for Reminyl® (now marketed as Razadyne®), a prescription drug known generically as galantamine hydrobromide. (Compl. ¶¶ 18-19). Among other patents, Janssen listed U.S. Patent No. 4,663,318 ("the '318 patent") in FDA's Orange Book in connection with NDA No. 21-169 for Reminyl®. (*Id.* ¶ 20).

In 2005, Mylan filed an ANDA seeking FDA approval to market generic galantamine hydrobromide tablets. (Compl. ¶¶ 7, 22-24). Mylan's ANDA contains a paragraph IV certification with respect to the '318 patent. (*Id.* ¶¶ 22, 31). As required by statute, Mylan notified Janssen of this paragraph IV ANDA filing. (*See id.* ¶ 22). In response, Janssen sued Mylan for alleged infringement of the '318 patent under 35 U.S.C. § 271(e)(2). (*Id.* ¶ 31). But, contrary to the Federal Circuit's decision in *Glaxo* and Judge Sleet's decision in *Allergan*, Janssen's complaint contains an improper claim for willful infringement based solely upon Mylan's filing of a paragraph IV ANDA. (*Id.* ¶¶ 31, 32, 34).

VI. ARGUMENT.

A. Janssen's Willful Infringement Claim Cannot Stand Under Controlling Federal Circuit Precedent.

A motion for judgment on the pleadings, like a motion to dismiss for failure to state a claim, must be evaluated solely on the facts alleged in the pleadings. *See Mele v. Fed. Reserve Bank of New York*, 359 F.3d 251, 257 (3d Cir. 2004). As such, a plaintiff's conclusory allegations or statements of law need not be accepted. *See CP Kelco U.S., Inc. v. Pharmacia Corp.*, No. CIV.A.01-240-RRM, 2002 WL 31230812, at *2 (D. Del. Sept. 19, 2002) (Thynge, M.J.) (Ex. E). In this Circuit, judgment on the pleadings is appropriate when "there is no material issue of fact to resolve, and [the moving party] is entitled to judgment in its favor as a matter of law." *Mele*, 359 F.3d at 253 (citation omitted); *see also Rodriguez v. Stevenson*, 243 F. Supp. 2d 58, 62, 70 (D. Del. 2002) (Sleet, J.) (granting motion for judgment on the pleadings pursuant to Rule 12(c)); *CP Kelco*, 2002 WL 31230812, at *2, *8 (same).

Here, this is not a close call because the Federal Circuit explicitly has held that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement," stating that it was "clear legal error" to conclude that the "mere

filing of an ANDA could form the basis of a willful infringement finding." *Glaxo*, 376 F.3d at 1350-51. Thus, even when viewed in the light most favorable to Janssen, its complaint contains no allegations that could support a finding of willful infringement. Indeed, by Janssen's own admissions, all Mylan has done is file an ANDA with a paragraph IV certification. (*See* Compl. ¶¶ 22, 31-34). Consequently, there simply is no set of facts set forth in the pleadings that would "entitle [Janssen] to the [willful infringement] relief requested," and Janssen's claim should be dismissed. *Rodriguez*, 243 F. Supp. 2d at 62 (citation omitted).

In *Glaxo*, the Federal Circuit held, using clear and unambiguous language, that 35 U.S.C. § 271(e)(2) solely "is designed to create an *artificial* act of infringement for purposes of establishing jurisdiction in the federal courts," precluding companies like Janssen from "hanging a finding of willfulness on such a special-purpose peg":

> ***[W]e now hold that the mere fact that a company has filed an ANDA application or [paragraph IV] certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4).*** The Supreme Court has emphasized that 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 271(e)(4) create an 'artificial' act of infringement only for a 'very limited and technical purpose that relates only to certain drug applications.' *Eli Lilly*, 496 U.S. at 676, 110 S. Ct. 2683. This purpose, as the Supreme Court explains, is to permit patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue. *Id.* at 624, 110 S. Ct. 2658; *see also* 35 U.S.C. § 271(e)(1) (exempting generic manufacturers from an infringement action when their use is for the purposes of developing and researching generic alternatives to obtain premarket approval by the FDA). In evaluating 35 U.S.C. § 271(e)(2), we have in our past decisions considered this provision to be primarily a jurisdictional-conferring statute that establishes a case or controversy in a declaratory judgment action. *See Allergan, Inc. v. Alcon Labs.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003) (stating that while § 271(e)(2) is not strictly a jurisdictional statute, it acts to permit a district court to exercise jurisdiction under 28 U.S.C. § 1338(a) in situations where an ANDA has been filed). The district court therefore erred in hanging a finding of willfulness on such a special-purpose peg.

> ***Because 35 U.S.C. § 271(e)(2) is designed to create an artificial act of infringement for purposes of establishing jurisdiction in the federal courts, we hold that the district court committed clear legal error in finding that Apotex's mere filing of an ANDA could form the basis of a willful infringement finding.***

Glaxo, 376 F.3d at 1350-51 (emphasis added). District courts uniformly have applied *Glaxo* to strike or dismiss willful infringement claims based solely on the filing of a drug application containing a paragraph IV certification. *See Allergan*, No. 04-968 (GMS), at 3-4 (striking Allergan's willful infringement claim from the complaint) (Ex. A); *Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc.*, 355 F. Supp. 2d 586, 591-93 (D. Mass. 2005) (granting Rule 12(c) motion for judgment on the pleadings dismissing claim for willful infringement against paragraph IV ANDA filer); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, No. 04-1689 (D.N.J. Apr. 18, 2005) (same) (Ex. F).

In *Allergan*, the patentee brought an infringement action against a company that filed a so-called "paper NDA" containing a paragraph IV certification.[3] In response to the defendant's motion to strike, the patentee argued that "the Federal Circuit's holding in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004) does not foreclose a claim for willful infringement in Abbreviated New Drug Application ("ANDA") or paper NDA cases." *Allergan*, No. 04-968 (GMS), at 2 (Ex. A). Judge Sleet soundly rejected the patentee's argument. (*Id.* at 3-4). Relying on the *Glaxo* decision, Judge Sleet explained that the "only act of infringement alleged in [the] complaint is [an] allegedly baseless paper NDA filing and Paragraph IV Certification," and held that "[b]ecause a paper NDA filing cannot be considered willful, [the] complaint does not state any basis under which it could assert a claim for willful infringement."

[3] A "paper NDA" is an application filed under 21 U.S.C. § 355(b)(2). Like an ANDA, the law requires a paper NDA application to contain a certification to Orange Book-listed patents in connection with the brand, NDA-drug. And like a paragraph IV ANDA, a paragraph IV paper NDA constitutes an artificial act of patent infringement sufficient to vest the courts with subject matter jurisdiction over the patent dispute.

(*Id.* at 4.) This Court should reject Janssen's willfulness claim for the same reason—the only act of infringement alleged in Janssen's complaint is Mylan's filing of an ANDA with a paragraph IV certification, and a paragraph IV ANDA cannot be considered willful. And while the *Glaxo* decision and Judge Sleet's ruling in *Allergan* provide this Court with ample authority to grant Mylan's motion, there is more.

In *Aventis*, the District of Massachusetts, citing *Glaxo*, granted the defendant's Rule 12(c) motion for judgment on the pleadings after finding the "only act of infringement alleged in Plaintiffs' amended complaint [was the defendant's] filing of an ANDA and a paragraph IV certification with the FDA." *Aventis*, 355 F. Supp. 2d at 592-93. In granting the ANDA-filer's motion, the court specifically dismissed the brand company's argument that the "act of filing a baseless paragraph IV certification to the FDA may be considered willful patent infringement." *Id.* at 591.

Similarly, in *Ortho-McNeil*, the plaintiff alleged that the defendants had willfully infringed its patents by filing a paragraph IV ANDA. (*See* 4/18/05 Oral Argument Tr. at 5-6 (Ex. G)). In response to the ANDA-filer's motion to dismiss, the brand company argued that it could allege willfulness as a basis for seeking attorneys' fees. (*Id.*) The court rejected this argument, finding it "fundamentally against the underlying rationale" of the Federal Circuit's *Glaxo* decision. (*Id.* at 7). The court noted that while the plaintiff could seek attorneys' fees, it could *not* do so by alleging that an ANDA filing constituted willful infringement. (*Id.* at 7-8). The court, agreeing with the reasoning in *Aventis*, granted defendants' judgment on the pleadings and dismissed the plaintiff's willful infringement claims. (*Id.* at 10); *Ortho-McNeil*, No. 04-1689, at 1 (Ex. F).

Like the complaints in *Glaxo*, *Allergan*, *Aventis*, and *Ortho-McNeil*, Janssen's complaint contains no set of facts that would entitle Janssen to any willful infringement relief. *Rodriguez*, 243 F. Supp. 2d at 62. Janssen alleges only that Mylan filed an ANDA with a paragraph IV certification. (Compl. ¶¶ 22, 31-34). But as the courts in *Glaxo*, *Allergan*, *Aventis*, and *Ortho-McNeil* have held, a paragraph IV ANDA filing cannot sustain a willful infringement claim. Indeed, Janssen has pled even fewer facts than presented in the *Glaxo*, *Allergan*, *Aventis*, and *Ortho-McNeil* complaints, as Janssen has not alleged (nor can it) that Mylan's paragraph IV certification was baseless or "wholly unjustified." Simply put, therefore, Janssen has not, and cannot, make a legally sufficient claim for willful infringement and its claim should be dismissed. *See Glaxo*, 376 F.3d at 1351 (holding that claim for willful infringement cannot be based on ANDA filing, even one purportedly containing a "wholly unjustified" paragraph IV certification).[4]

B. In The Alternative, Janssen's Willfulness Claim Should Be Bifurcated, And Discovery Stayed, Pending A Decision On Liability Because Such Relief Avoids Prejudice And Serves Judicial Economy.

Pursuant to Rule 42(b), this Court may order separate trials on distinct claims or issues to promote "convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy . . . ." FED. R. CIV. P. 42(b). The furtherance of any one of these important goals provides sufficient justification for a court to order bifurcation and a stay of discovery. *See* 8 JAMES W. MOORE ET AL., MOORE'S FEDERAL PRACTICE § 42.20[4][a] (3d ed. 2005 (Lexis)). In this case, bifurcation and a stay of discovery on Janssen's willfulness claim advances not one, but all of these goals.

[4] If Mylan launches its products before completion of this litigation, Janssen could seek to re-plead its willful infringement claim. Thus, dismissal here, at this stage of the proceedings, would not only be consistent with controlling Federal Circuit law, but in no way would prejudice Janssen.

1. Only Bifurcation And A Stay Of Willfulness Discovery Will Prevent Substantial And Irreparable Prejudice To Mylan.

In *Quantum*, the Federal Circuit stressed that bifurcation and a discovery stay on willfulness claims are necessary to avoid the severe and inevitable prejudice caused when the accused infringer is forced to choose between: (a) relying on the advice-of-counsel defense (to disprove claims of willful infringement); and (b) waiving the attorney-client privilege (to avoid revealing highly sensitive, confidential litigation strategies). *Quantum*, 940 F.2d at 643-44. Consequently, courts addressing this issue, the so-called "*Quantum*-dilemma," routinely bifurcate willfulness from liability and stay such discovery.

To succeed on a charge of willful infringement, the patentee must show by clear and convincing evidence that, given the totality of the circumstances, "the infringer acted in disregard of the patent . . . [and] had no reasonable basis for believing it had a right to do the [infringing] acts." *Am. Med. Sys., Inc. v. Med. Eng'g Corp.*, 6 F.3d 1523, 1530 (Fed. Cir. 1993) (citation and internal quotations omitted). If willful infringement is proven, the patentee could be entitled to enhanced damages and attorneys fees under 35 U.S.C. §§ 284, 285. *See Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1377-78 (Fed. Cir. 2002).

"[G]ood faith reliance on the competent advice of counsel" is a defense to a charge of willful infringement. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1579 (Fed. Cir. 1996) (citation omitted). Asserting this defense, however, has profound ramifications for the accused infringer—it constitutes a waiver of the attorney-client privilege with respect to any opinion of counsel upon which the accused infringer intends to rely regarding the patent at issue. *See Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048, 1056-57 (Fed. Cir. 1994); *Quantum*, 940 F.2d at 643-44. If the waiver occurs prior to a finding of liability, the accused infringer suffers enormous prejudice, having waived privilege and provided the patentee with a

roadmap to its defenses and legal theories. *See Quantum*, 940 F.2d at 644; *In re Recombinant DNA Tech. Patent & Contract Litig.*, 30 U.S.P.Q.2d 1881, 1900 (S.D. Ind. 1994) (stating that waiving the privilege is "'tantamount to providing the foundation of a party's whole litigation strategy to its opponent'").

The Federal Circuit recognizes the dire consequences that a willfulness allegation has for the accused infringer, stressing that district courts should give "serious consideration" to bifurcating willfulness from liability to avoid forcing a defendant to pick between waiving privilege and risking a willfulness finding. *Quantum*, 940 F.2d at 643-44. Indeed, the court warns that:

> Proper resolution of [this] dilemma . . . is of great importance not only to the parties but to the fundamental values sought to be preserved by the attorney-client privilege. An accused infringer . . . should not, without the trial court's careful consideration, be forced to choose between waiving the privilege in order to protect itself from a willfulness finding, in which case it may risk prejudicing itself on the question of liability, and maintaining the privilege, in which case it may risk being found to be a willful infringer if liability is found.

Id.

Given this dilemma, "[t]he Federal Circuit encourages bifurcation when a party is faced with [this choice] . . . known as the 'Quantum dilemma . . . .'" *Aptargroup, Inc. v. Owens-Illinois, Inc.*, No. 02 C 5058, 2003 WL 21557632, at *1 (N.D. Ill. July 3, 2003) (Ex. H); *Sage Prods., Inc. v. Devon Indus., Inc.*, No. 93-2403 RG(CTX), 1994 WL 791601, at *2-*3 (C.D. Cal. Jan. 25, 1994) (same) (Ex. I). Indeed, the failure to grant separate trials on willfulness and liability can result in reversal: "While our court has recognized that refusal of a separate trial will not require reversal in every case involving attorney client communications bearing on willfulness, we have suggested the advisability of separate trials in appropriate cases." *Quantum*, 940 F.2d at 644.

It is no surprise, therefore, that bifurcation in patent cases "has become common." *Ciena Corp. v. Corvis Corp.*, 210 F.R.D. 519, 521 (D. Del. 2002) (Farnan, J.) (citation omitted); *Yamaha Hatsudoki Kabushiki Kaisha v. Bombardier Inc.*, 59 U.S.P.Q.2d 1088, 1090 (C.D. Cal. 2001) (same). Since the *Quantum* decision, district courts confronted with an accused infringer facing a *Quantum* dilemma routinely have bifurcated and stayed discovery on willfulness claims pending resolution of liability. *See, e.g.*, *Arthrocare*, No. 01-504-SLR, slip op. at 3 (Robinson, C.J.) (same) (Ex. D); *St. Clair*, 2002 WL 1901268, at *2 (Farnan, J.) (bifurcating and staying discovery on willfulness) (Ex. C); *aaiPharma, Inc. v. Barr Labs., Inc.*, No. 7:01-CV-150-F1, slip op. at 2-3 (E.D.N.C. Sept. 9, 2002) (same) (Ex. J); *Lear Corp. v. Bertrand Faure Technical Ctr., Inc.*, No. 00-CV-72895, slip op. at 12 (E.D. Mich. Sept. 4, 2001) (same) (Ex. K); *Novopharm Ltd. v. TorPharm, Inc.*, 181 F.R.D. 308, 312 (E.D.N.C. 1998) (same); *Princeton Biochemicals, Inc. v. Beckman Instruments, Inc.*, 180 F.R.D. 254, 260-61 (D.N.J. 1997) (same); *Thomcast, A.G. v. Cont'l Elecs. Corp.*, No. 94-G-2486-S, slip op. at 1-2 (N.D. Ala. Apr. 24, 1995) (same) (Ex. L); *Recombinant DNA*, 30 U.S.P.Q.2d at 1900-01 (same); *Sage Prods.*, 1994 WL 791601, at *3 (same) (Ex. I); *B. Braun Med. Inc. v. Abbott Labs.*, 32 U.S.P.Q.2d 1211, 1215-16 (E.D. Pa. 1994) (same).

Indeed, this is particularly true in Hatch-Waxman ANDA litigation, such as Janssen's suit here, where the statute imposes an affirmative duty on the parties to cooperate in expediting resolution of the litigation. *See, e.g.*, *Eli Lilly & Co. v. Barr Labs., Inc.*, No. 1:02-CV-1844-SEB, slip op. (S.D. Ind. Mar. 31, 2004) (bifurcating and staying discovery on willfulness in an ANDA case) (Ex. M); *SmithKline Beecham Corp. v. Teva Pharms. USA, Inc.*, No. 02-3779(JWB), slip op. at 7-16 (D.N.J. Mar. 5, 2003) (same) (Ex. N); *Ortho-McNeil v. Teva Pharms. USA*, No. 02-2794(GEB), slip op. at 4-8 (D.N.J. Jan. 28, 2003) (same) (Ex. O);

Pharmacia Corp., 2002 WL 1268047, at *2 n.1 (Robinson, C.J.) (same) (Ex. B); *Pfizer Inc. v. Novopharm Ltd.*, 57 U.S.P.Q.2d 1442, 1445 (N.D. Ill. 2000) (same); *Eli Lilly & Co. v. Barr Labs., Inc.*, No. IP 96-0491-C-B/S, slip op. at 2-3 (S.D. Ind. Oct. 29, 1998) (same) (Ex. P); *Bayer AG v. Barr Labs., Inc.*, No. 92 Civ. 0381 (WK), slip op. at 1 (S.D.N.Y. Sept. 11, 1995) (same) (Ex. Q).

Mylan faces the very prejudice that the Federal Circuit warned about in *Quantum*. Absent bifurcation and a stay, Mylan would be forced into the no-win situation of (1) asserting attorney-client privilege, or (2) mounting the advice-of-counsel defense to willful infringement. By asserting privilege, Mylan risks a willful infringement finding, despite its belief that Janssen's willfulness claim is meritless. But, relying on the advice-of-counsel defense forces Mylan to waive privilege and risk defeat on liability because it would have "to provide [Janssen] with a 'detailed work product road map'" to Mylan's patent attorneys' confidential legal advice. *Recombinant DNA*, 30 U.S.P.Q.2d at 1900 (internal quotation marks omitted). Mylan suffers substantial prejudice either way.

Bifurcation of willfulness from liability and a stay of discovery related to willfulness is the only way to prevent Mylan from facing these dilemmas—and from suffering severe prejudice. On the basis of this prejudice alone, bifurcation and a stay of discovery are warranted in this case. *See St. Clair*, 2002 WL 1901268, at *2 (ordering bifurcation and a stay of discovery as to willfulness because of undue prejudice to alleged infringer) (Ex. C); *Pharmacia Corp.*, 2002 WL 1268047, at *2 n.1 (Ex. B); *SmithKline Beecham*, No. 02-3779(JWB), slip op. at 7-16 (Ex. N); *Ortho-McNeil*, No. 02-2794(GEB), slip op. at 5-6 (Ex. O); *Princeton Biochemicals*, 180 F.R.D. at 260-61; *United States Gypsum Co. v. Nat'l Gypsum Co.*,

No. 89 C 7533, 1994 WL 74989, at *2-*3 (N.D. Ill. Mar. 10, 1994) (Ex. R); *Sage Prods.*, 1994 WL 791601, at *2-*3 (Ex. I).

2. The Lack Of Any Significant Overlapping Issues Between Liability And Willfulness, As Well As The Lack Of Any Prejudice To Janssen, Also Make Bifurcation And A Stay Of Discovery Appropriate Here.

The lack of significant evidentiary overlap between liability and willfulness, as well as the lack of prejudice to Janssen, also weigh heavily in favor of bifurcating and staying discovery on Janssen's willfulness claim. Because "liability is a function of the objective validity" of the patent, while willfulness is a function of the accused infringer's "subjective intent," there typically are few overlapping issues of proof between liability and willfulness. *Pfizer*, 57 U.S.P.Q.2d at 1444; *see also TorPharm*, 181 F.R.D. at 312 ("[T]here is no significant overlap between issues of liability for patent infringement and willfulness . . . ."); *Princeton Biochemicals*, 180 F.R.D. at 258 & n.3 (recognizing that "a determination regarding patent infringement[] does not require a detailed inquiry into the elements of willful infringement" and further that "patent infringement generally requires proof that an individual or entity, without authority makes, uses, offers to sell, sells or imports the patented invention within the United States, its territories, or its possessions during the term of the patent . . ., while a determination of willful infringement focuses on the intent of the infringer" (internal citation omitted)).

This case is no exception. As it stands now, the liability trial would focus on objective issues of patent validity. The proof needed to resolve liability is entirely different than the evidence needed for willfulness. The liability trial will focus on objective technical and factual issues concerning, for instance, what the relevant universe of prior art teaches. Should Janssen ultimately prevail on liability and go forward on willfulness, that trial would focus exclusively on Mylan's state of mind at the time of the alleged infringement. Significantly, with

no overlap of issues, Janssen will suffer no prejudice if willfulness is bifurcated and discovery is stayed.[5]

3. Bifurcation And A Stay Of Discovery Will Expedite Resolution Of This Hatch-Waxman Case And Conserve Judicial Resources.

Bifurcating and staying willfulness discovery not only prevent substantial prejudice to the alleged infringer, but such relief also promotes judicial efficiency by preventing a potentially massive waste of resources. Issues relating to willful infringement typically are complex, resource-draining, and expensive to litigate. Again, this case would be no exception. For example, to the extent that a Defendant in this consolidated case relies on the advice-of-counsel defense, the parties undoubtedly will have disputes about (a) whether particular privileged documents are discoverable, including issues related to the scope of the waiver caused by assertion of the advice-of-counsel defense; (b) whether individual depositions may proceed, potentially including depositions of that Defendant's patent counsel; and (c) the proper scope of any depositions that might take place on willfulness issues. Because such disputes involve the highly-charged issue of privilege, they inevitably entail extensive briefing. Resolving such ancillary discovery matters is costly, both in terms of efficiency and resources, and should be avoided, especially in Hatch-Waxman cases. If Defendants succeed on liability, however, discovery disputes on willfulness would be entirely unnecessary. At a minimum, such discovery is postponed to a more convenient time.

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[5] Even if there was some minor overlap of issues, bifurcation still is appropriate in this case because the overlap would not outweigh the severe prejudice Mylan would suffer in the absence of bifurcation and a stay of discovery. *See Lemelson v. Apple Computer Inc.*, 28 U.S.P.Q.2d 1412, 1423 (D. Nev. 1993) (ordering bifurcation of liability and damages because minimal overlap "provide[d] no reason to deny bifurcation"); *Amsted Indus. Inc. v. Nat'l Castings Inc.*, 16 U.S.P.Q.2d 1737, 1739-40 (N.D. Ill. 1990) (ordering bifurcation of liability and willfulness despite overlap of issues because overlap did not outweigh advantages of bifurcation); *Paine Webber, Jackson & Curtis, Inc. v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 587 F. Supp. 1112, 1117 (D. Del. 1984) (ordering bifurcation of liability and damages despite overlap of issues).

Bifurcating and staying willfulness discovery, therefore, will avoid substantial prejudice to Mylan and conserve judicial resources because "willfulness is not part of the liability finding, and the issue need not be reached if the patent is found invalid or not infringed." *Lemelson*, 28 U.S.P.Q.2d at 1423 (citation omitted). And courts have found that the mere possibility of saving such substantial resources is reason enough to order bifurcation and a stay of discovery. *See Rohm & Haas Co. v. Mobil Oil Corp.*, 654 F. Supp. 82, 86 (D. Del. 1987) ("If this Court grants [the motion to bifurcate], some potential conflicts, the resolution of which could require considerable efforts by the Court and parties, may be avoided or at least postponed" until after the liability phase of the trial, thereby promoting "economy, convenience, and expediency"), *aff'd*, 895 F.2d 1421 (Fed. Cir. 1990); *Pfizer*, 57 U.S.P.Q.2d at 1445 (bifurcating willfulness from liability "because a finding of no liability would obviate the need for discovery and trial on the willfulness issue"); *TorPharm*, 181 F.R.D. at 312 ("One of the purposes of bifurcation under Rule 42(b) is to defer costly discovery and trial preparation costs pending the resolution of preliminary liability issues." (citation omitted)); *Princeton Biochemicals*, 180 F.R.D. at 260-61 (ordering bifurcation and a stay of discovery in part because of "concerns regarding the potentially unnecessary expense and effort involved in adjudicating the willfulness and damages issues before a finding of liability"); *Recombinant DNA*, 30 U.S.P.Q.2d at 1901 (bifurcating and staying willfulness discovery in part to minimize the use of valuable court time by deferring issues concerning whether "particular documents are discoverable or protected by the attorney-client privilege" (citation omitted)); *cf. Paine Webber*, 587 F. Supp. at 1117 ("The Court further finds it to be in the interest of expedition and economy to defer costly and possibly unnecessary discovery proceedings on the damages issues pending the resolution of the liability issues." (citation omitted)).

Unquestionably, bifurcation and a discovery stay will further expedite resolution of this substantially narrowed Hatch-Waxman patent litigation. Such relief will promote judicial economy. It also will simplify trial on the issues related to liability. And it will do all of these things while avoiding severe prejudice to Mylan, and the other Defendants.

VII. CONCLUSION.

For all these reasons, the Court should grant Mylan's Rule 12(c) motion for judgment on the pleadings and dismiss Janssen's claim for willful infringement. Alternatively, this Court should bifurcate, and stay discovery on, Janssen's willfulness claim in order to avoid prejudicing Mylan and to serve the interest of judicial economy in this Hatch-Waxman case—a case where the parties have an affirmative, statutory duty to expedite its resolution.

Dated: December 13, 2005.

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MYLAN LABORATORIES INC.

By: *__/s/ Mary B. Matterer__*

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CERTIFICATE OF SERVICE

I hereby certify that on the 13th day of December, 2005, I electronically filed the foregoing document, **MEMORANDUM IN SUPPORT OF DEFENDANT MYLAN'S RULE 12(c) MOTION FOR JUDGMENT ON THE PLEADINGS DISMISSING JANSSEN'S WILLFUL INFRINGEMENT CLAIM OR, IN THE ALTERNATIVE, TO BIFURCATE AND STAY DISCOVERY ON SUCH CLAIM**, with the Clerk of the Court using CM/ECF, which will send notification to the following:

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